

## EXHIBIT 164

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**From:** Ehrlinspiel, Jason (USAALN) <Jason.Ehrlinspiel@usdoj.gov>  
**Sent:** Tuesday, September 30, 2014 9:46 AM  
**To:** Hernandez, Tracey  
**Cc:** Wood, Justin G. (DEA); Dugans, Larry G. (DEA)  
**Subject:** EXTERNAL: Notice of Civil Violations  
**Attachments:** Notice of Violations Letter to Generics Bidco 9.30.14.pdf

Ms. Hernandez,

Please find attached the Notice of Intent to Seek Civil Penalties.

Please do not hesitate to call or email should you have any questions.

Regards,

Jason Ehrlinspiel

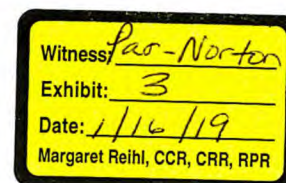
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September 30, 2014

*Via Email*

Tracey Hernandez  
Director, DEA Compliance  
Generics Bidco I, LLC  
130 Vintage Drive  
Huntsville, Alabama 35811

In re: Notice of Violations of Record Keeping of Regulated Controlled Substances and  
Civil Fine Exposure – Generics Bidco I, LLC

Dear Ms. Hernandez:

Our office is currently investigating allegations under the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, related to Generics Bidco I, LLC (hereinafter referred to as “GB”) failure to keep complete and accurate records of controlled substances and diversion of controlled substances in violation of 21 U.S.C. § 842(a), 21 C.F.R. § 1304.21(a), 21 C.F.R. § 1305.13(b) & (d), and 21 C.F.R. § 1305.17(c). Pursuant to our September 22, 2014 telephone conference, you have agreed to accept this notice via email.

The Drug Enforcement Administration (DEA) conducted an accountability audit for the period of December 31, 2012 through July 14, 2014. In conducting the audit, the DEA used GB’s Bi-Annual Controlled Item Inventory, which was dated the close of business December 31, 2012. Initially, the DEA discovered that GB’s Bi-Annual Controlled Item Inventory improperly mixed the schedule II controlled substances with the schedules III-V. The audit revealed alarming deviations of schedule II and III controlled substances. In violation of 21 C.F.R. § 1304.21(a) and 21 USC § 827(a)(3), GB failed to account for and properly maintain records of the following:

1. Hydrocodone 10/325 mg – 1,184 bottles and 694 tablets
2. Hydrocodone 7.5/325 mg – 1,326 bottles
3. Hydrocodone 7.5/200 mg – 12 bottles
4. Hydrocodone 5/325 mg – 6,318 bottles
5. Carisoprodol 350 mg – 243 bottles and 2 tablets
6. Oxycodone 30 mg – 816 bottles and 4 tablets
7. Meperitab 50 mg – 83 bottles and 79 tablets

Overall, GB’s deviations total several million tablets. It is important to note that the DEA only audited 8 controlled substances.

The investigation revealed the following violations by GB:

Tracey Hernandez  
September 30, 2014

1. Failure to maintain complete and accurate records in violation of 21 C.F.R. § 1304.21 (a); The DEA's inspection revealed an overall careless and haphazard record-keeping practice at GB, as demonstrated by, among other things, deviations exceeding 9 million tablets in 7 of 8 of the audited controlled substances.
2. Failure to maintain separate inventories for Schedule II controlled substances from Schedule III-V controlled substances in violation of 21 C.F.R. § 1304.04 (f)(i); and
3. Failure to keep records readily retrievable in violation of 21 C.F.R. § 1304.04 (f)(2).

GB's recordkeeping violations, in particular as evidenced by the several million tablet deviation are egregious and evidence a complete disregard of GB's statutory and regulatory obligations.

Under the 1998 amendments to the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, persons who negligently fail to make, keep, or furnish required records, are liable for a civil penalty of up to \$10,000 per violation. As outlined above, GB is potentially subject to civil penalties that may amount to millions of dollars. Our office is prepared to institute proceedings for the civil prosecution of GB's violations. Prior to beginning such proceedings, our office is willing to discuss the amount of the civil fine and other corrective measures. If GB desires to take advantage of this opportunity, please contact me by October 9, 2014. I look forward to hearing from you soon.

Sincerely,

JOYCE W. VANCE  
United States Attorney



By:

JASON EHRLINSPIEL  
Assistant U.S. Attorney

Cc: Larry Dugans, DI, DEA  
Justin Wood, SDI, DEA